



[BILLING CODE 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed collection, 60-day comment request: Certificate of Confidentiality Electronic Application System (OD)

SUMMARY: In compliance with the requirements of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the Office of Extramural Research (OER), the National Institutes of Health (NIH) will continue the use of the electronic application form for the submission of requests to the NIH for Certificates of Confidentiality (CoCs), which was launched in 2015.

DATES: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Dr. Ann M. Hardy, NIH Extramural Human Research Protections Officer and Coordinator, Certificates of Confidentiality, Office of Extramural Programs, OER, NIH, 3701 Rockledge Dr, Room 3002, Bethesda, MD 20892, or call non-toll-free number (301) 435-2690, or E-mail your request, including your address to: hardyan@od.nih.gov. Formal requests for additional plans and instruments must be requested in writing.

SUPPLEMENTARY INFORMATION: Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance

of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

PROPOSED COLLECTION: Certificate of Confidentiality Electronic Application System 0925-0689, expiration date 01/30/2017, Office of Extramural Research (OER), National Institutes of Health (NIH).

Need and Use of Information Collection: This application system provides one electronic form to be used by all research organizations that wish to request a Certificate of Confidentiality (CoC) from the NIH. As described in the authorizing legislation (Section 301(d) of the Public Health Service Act, 42 U.S.C. §241(d)), CoCs are issued by the agencies of Department of Health and Human Services (HHS), including the NIH, to authorize researchers conducting sensitive research to protect the privacy of human research subjects by enabling them to refuse to release names and identifying characteristics of subjects to anyone not connected with the research. At the NIH, the issuance of CoCs has been delegated to the individual NIH Institutes and Centers (ICs). To make the application process consistent across the entire agency, OER launched an electronic application system in 2015 that is used by research organizations that wish to request a CoC from any NIH IC. Having one system for all CoC applications to the NIH is more efficient for both applicants and NIH staff who process these requests. The NIH

uses the information in the application to determine eligibility for a CoC and to issue the CoC to the requesting organization. It is anticipated that the NIH ICs will issue approximately 1300 new CoCs each year for eligible research projects.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total annualized burden hours estimate is 1,951.

Estimated Annualized Burden Hours

Type of Respondents	Number of Respondents	Frequency of Response	Average Time per Response (in hours)	Total Annual Burden Hours
CoC Applicants-Private	455	1	90/60	683
CoC Applicants-State/local	650	1	90/60	975
CoC Applicants-Small business	130	1	90/60	195
CoC Applicants-Federal	65	1	90/60	98
Total:	1,300	1,300		1,951

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